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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.				
10/510,609	10/08/2004	Annette Kim	21076YP	4963				
210 MERCK AND CO., INC P O BOX 2000 RAHWAY, NJ 07065-0907	7590 07/11/2007		<table border="1"><tr><td colspan="2">EXAMINER</td></tr><tr><td colspan="2">DESAI, RITA J</td></tr></table>		EXAMINER		DESAI, RITA J	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/510,609	<b>Applicant(s)</b> KIM, ANNETTE	
	<b>Examiner</b> Rita J. Desai	<b>Art Unit</b> 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 7-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Claims 1-21 are pending.

Claim 1-5 compound claims were previously examined.

Claims 6-21 were withdrawn.

The examiner has rejoined the pharmaceutical composition claim 6.

The pending claims are now 1-6 and claims 7-21 are withdrawn .

The rejection of claim 1-5 ( now the rejection is on claims 1-3,5 and 6 )under 35 USC 112 still stands.

Applicants have amended the claims such that V is an aryl or a heterocyclo, however heterocyclo covers a large scope and applicants example of benzofuran, benzodioxo and oxazolo is not sufficient guidance to cover all the hetero cyclo.

Also it should be noted that q can be zero in which case the aryl and heterocyclic ring is absent.

Also applicants terms "substituted " can be drawn to any group. The phrase not only is not fully described , but with examples of only Br and hydrogen is not fully enabled. Page 18 of the specification does have some examples of the substituents however with the art being so unpredictable applicants should have made more and given more guidance with respect to the activity.

The pharmaceutical art is highly unpredictable.

See *In re Fisher*, 166 USPQ 18, at 24 (In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely

Art Unit: 1625

with the degree of unpredictability of the factors involved.), *Nationwide Chemical Corporation, et al. v. Wright, et al.*, 192 USPQ 95 (one skilled in chemical and biological arts cannot always reasonably predict how different chemical compounds and elements might behave under varying circumstances), *Ex parte Sudilovsky* 21 USPQ2d 1702 (Appellant's invention concerns pharmaceutical activity. Because there is no evidence of record of analogous activity for similar compounds, the art is relatively unpredictable) *In re Wright* 27 USPQ2d 1510 (the physiological activity of RNA viruses was sufficiently unpredictable that success in developing specific avian recombinant virus vaccine was uncertain).

The scope of the claims involves thousands of compounds, "substituted" by a laundry list of groups.

All the compounds teach away from all these substituents. R is H in all the examples given.


In view of the unpredictable nature of pharmaceutical art applicants need to provide more guidance.

Even a change from H to a methyl group changes the properties of a compounds.

Applicants claims are drawn to treating cancer which ( let alone just one specific cancer such as lung cancer) which is even more unpredictable. Thus with so many variables involved, the scope of the compounds and the scope of the treating , applicants have not given any data that the compounds are indeed "pharmaceutical" i.e. can treat a disorder.

Also a search on the Aldrich catalogue gave on 13 hits of reagents with MgBr.

Art Unit: 1625

Sorting Options: Relevancy 

**3-Chloro-5-fluorophenylmagnesium bromide solution (1)**

**4-Chloro-3-fluorophenylmagnesium bromide solution (1)**

**4-Chloro-2-methylphenylmagnesium bromide solution (1)**

**3-Fluoro-4-methylphenylmagnesium bromide solution (1)**

**4-Fluoro-2-methylphenylmagnesium bromide solution (1)**

**4-Fluoro-3-methylphenylmagnesium bromide solution (1)**

**5-Fluoro-2-methylphenylmagnesium bromide solution (1)**

**3-Fluoro-4-methoxyphenylmagnesium bromide (1)**

**5-Fluoro-2-methoxyphenylmagnesium bromide solution (1)**

**Isopropenylmagnesium bromide solution (2)**

Art Unit: 1625

**4-Methoxy-2-methylphenylmagnesium bromide solution (1)**

**1-Methyl-1-propenylmagnesium bromide solution (1)**

Thus all the reactants to make the compounds are not commercially available and applicants have not shown how to make them either.

Thus the rejection still stands.

The rejection of claims 1-3 under 35 USC 102 over Belanger et al US 4332810 still stands. Even though applicants have amended the claims to V being a n aryl or an heterocyclic group, but when the term q is 0 the compounds still can read on the compounds of the prior art as V is H , n and p also can both be zero and R is an substituted alkyl. or H In the definition of substituents it includes aryl.

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the provisional Double patenting over US 10/510611 still stands as applicants have not provided a terminal disclaimer.

### ***Conclusion***

Claims 1-3,5 and 6 stand rejected.

Art Unit: 1625

Claims 7-21 are withdrawn.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, flex time..

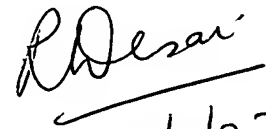
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Art Unit: 1625

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rita J. Desai  
Primary Examiner  
Art Unit 1625

  
7/3/07

R.D.  
July 2, 2007